

REMARKS

Claims 1 and 44-53 are pending. Claims 1, 44-47, and 50-52 are withdrawn as being drawn to a non-elected invention. Claims 48, 49, and 53 stand rejected under 35 U.S.C. § 112, first paragraph. Claim 48 also stands objected to because of informality. This rejection and objection are addressed in detail below.

Rejection under 35 U.S.C. § 112, first paragraph

As an initial matter the Office notes that “[an] adequate written description requires both structure and function to identify members of a genus.” To address this issue, applicants have amended claim 48 to recite that the claimed polypeptides have the functional characteristic of being virulence factors. Support for this amendment is found throughout the specification. In particular, the claimed polypeptides have identity to a polypeptide encoded by orf19544 which is part of the 33A9 locus. The 33A9 locus was identified by applicants as present in several highly pathogenic *P. aeruginosa* clinical isolates and is part of a pathogenicity island (see, for example, page 39, lines 5-8 and lines 21-23). Given the current amendment and that applicants’ specification teaches a pathogenic functional characteristic of the claimed polypeptide, this basis of the rejection should be withdrawn.

The Office further argues that applicants’ predicted start and stop codons are not described in the originally filed specification and therefore, absent a specific disclosure

pointing out the precise start and stop codons, constitutes new matter. Applicants first note that SEQ ID NO.: 252 encodes a single polypeptide of 640 amino acids, and that while multiple start codons and stop codons are in fact present in SEQ ID NO.: 252, one skilled in the art would recognize that SEQ ID NO.: 252 encodes one open reading frame that encodes a full length polypeptide. In addition, applicants note that the case law makes clear that a specification need not identically describe the claimed subject matter, as seemingly required by the Office in this case. Rather, as stated in *In re Edwards*, 568 F.2d 1349, 1351-1352, 196 U.S.P.Q. 465, 467 (C.C.P.A. 1978):

To comply with the description requirement it is not necessary that the application describe the claimed invention in *ipsis verbis*, [citation omitted]; all that is required is that it reasonably convey to persons skilled in the art that, as of the filing date thereof, the inventor had possession of the subject matter later claimed by him. [citation omitted.]

Applicants have plainly satisfied this standard. The claims in question, as presently amended, cover polypeptides which are virulence factors. Given that SEQ ID NO.: 252 encodes one and only one polypeptide, the claimed polypeptide itself is adequately described in applicants' specification and reasonably conveys that, as of the filing date thereof, the inventors had possession of the subject matter later claimed by them. Reliance on an open-reading frame of a full-length polypeptide that is readily recognized by the skilled worker cannot constitute new matter. In short, applicants' written description is consistent with the pending claims, and for all of the above reasons, applicants request reconsideration and withdrawal of this basis of the rejection.

In response to the Office's assertion that the scope of the claims includes numerous structural variants, applicants note that the present claim amendment recites a functional limitation that distinguishes the claimed polypeptides from other polypeptides.

As stated in the Written Description Guidelines (66 FR 1106),

[f]actors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient.

As noted above, the claimed polypeptides are distinguished from other polypeptides by both the structural characteristic of having at least 90% sequence identity to SEQ ID NO.:252 and by the specific functional characteristic of being a virulence factor. As clear distinguishing characteristics that are shared by the claimed polypeptides are disclosed in applicants' specification, this basis of the rejection should also be withdrawn.

Finally, the Office notes that applicants have claimed a polypeptide encoded by SEQ ID NO.: 252 without identifying a full-length open reading frame. Applicants disagree. As noted above, SEQ ID NO.: 252 encodes one open reading frame that encodes a full length polypeptide, and applicants' claims have been amended accordingly. Support for this amendment is found in the specification, for example, at page 73, line

- 23. This basis of the rejection should also be withdrawn.

Claim Objections

Claim 48 stands objected to as reciting “has a least 90%” identity.” This typographical error has been corrected by the present amendment.

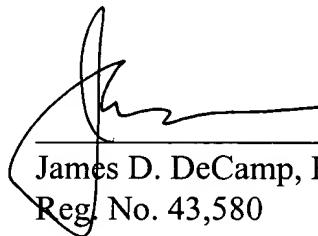
CONCLUSION

Applicants submit that the claims are now in condition for allowance and such action is respectfully requested.

Enclosed is a Petition to extend the period for replying to the Office action for three months, to and including December 27, 2004, and a check in payment of the required extension fee. Applicants also enclose a Notice of Appeal.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,



James D. DeCamp, Ph.D.
Reg. No. 43,580

Date: 27 December 2004
Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045